IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

(1) TULSA CANCER INSTITUTE, PLLC, an Oklahoma Professional Limited Liability Company, now known as Oklahoma Cancer Specialists Management Company, LLC; (2) OKLAHOMA ONCOLOGY & HEMATOLOGY, INC., an Oklahoma Corporation, dba CANCER CARE ASSOCIATES; (3) STATE of OKLAHOMA ex rel., BOARD of REGENTS for the STATE of OKLAHOMA; (4) TEXAS ONCOLOGY, P.A., a Texas Professional Association; on behalf of themselves and all others similarly situated, Plaintiffs, v. (1) GENENTECH INC., a California Corporation, Defendant.	MDL DOCKET NO. 16-MD-2700 Document Relates to: Case No. 15-CV-157-TCK-TLW Jury Trial Demanded

THIRD AMENDED COMPLAINT

The Plaintiffs, individually and as representatives of a class of persons and entities located in the United States, pursuant to Fed. R. Civ. P. 23 and the Class Action Fairness Act of 2005, allege and state:

Jurisdiction and Venue

The Plaintiffs

1. At times relevant to this action, Tulsa Cancer Institute, PLLC ("TCI"), now known as Oklahoma Cancer Specialists Management Company, LLC, was an Oklahoma professional limited liability company with its principal place of business in Tulsa, Oklahoma.

2. At times relevant to this action, Oklahoma Oncology & Hematology, Inc., now known as Oklahoma Cancer Specialists and Research Institute, was an Oklahoma corporation doing business as Cancer Care Associates ("CCA") with its principal place of business in Tulsa, Oklahoma.

3. The State of Oklahoma ex rel., Board of Regents of the State of Oklahoma acts for and on behalf of the University of Oklahoma Stephenson Cancer Center. The University of Oklahoma Stephenson Cancer Center's principal place of business is Oklahoma City, Oklahoma.

4. Texas Oncology, P.A., is a Texas professional association with its principal place of business in Dallas, Texas and clinics located in Oklahoma and Texas.

The Defendant

5. Defendant Genentech Inc. ("Genentech") is a California corporation with its principal place of business in San Francisco, California.

Jurisdiction and Venue

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 and the Class Action Fairness Act of 2005. Complete diversity exists among each Plaintiff and the Defendant, there are more than 100 class members and the aggregate amount in controversy exceeds $5,000,000.

7. The Defendant is subject to this Court's personal jurisdiction.

8. Venue is proper in the Northern District of Oklahoma pursuant to 28 U.S.C. § 1391.

9. Plaintiffs TCI and CCA reside in this judicial district.

10. The claims asserted herein arise out of Defendant's acts or omissions that occurred in this judicial district.

Summary of Plaintiffs' Claims

11. Each Plaintiff organization provides or provided healthcare services specializing in the diagnosis and treatment of cancer. Each Plaintiff purchased a cancer treatment drug known as Herceptin which was manufactured and distributed by the Defendant Genentech. Each

Plaintiff suffered damages caused by Genentech's breach of warranties concerning the advertising, labeling and delivery of the true volume and density of Herceptin available in the vials Plaintiffs purchased.

12. Herceptin is distributed in containers (vials) which are represented by Genentech to contain 440 milligrams (mg) of lyophilized (dehydrated or "freeze-dried") medicine. To administer the medicine, the Herceptin product is mixed, pursuant to directions provided by Genentech, with a liquid (diluent), also provided to end users by Genentech. After mixing the lyophilized medicine and the diluent, Genentech claims the resulting fluid contains 440 mg of Herceptin at a concentration of 21 mg/mL.

13. 440 mg concentrated at 21 mg/mL would provide 20.952 mL of fluid solution.

14. Plaintiffs have discovered that after mixing the lyophilized medicine with the diluent, the actual volume yielded for use by Plaintiffs in treating their patients is never more than 20.2 mL.

15. This shortage is caused either by a lower amount of Herceptin being provided than advertised or a higher concentration of Herceptin after mixing than advertised.

16. The 20.2 mL, rather than 20.952 mL, could be caused by Genentech providing 424 mg of Herceptin instead of the 440 mg represented and warranted by Genentech.

17. The 20.2 mL, rather than 20.952 mL, could be caused by Genentech inaccurately representing and warranting the concentration of the mixed fluid solution as 21 mg/mL when it really is 21.8 mg/mL.

18. Genentech's internal emails acknowledge that the represented concentration is not accurate. Genentech's Production Engineer explained to his internal audience that Genentech's own internal technical report showed a concentration of 21.8 mg/ml. *See* Email from Tom White to Olivia Ware and William Henry Smith (Sept. 25, 2002) (Ex. 1). However, Genentech made the calculated decision to represent the concentration as 21 mg/ml and thus require physicians and practice groups to buy more product.

19. Regardless the cause of the discrepancy, Plaintiffs do not receive 20.952 mL of fluid solution after following Genentech's direction despite paying for a quantify of 20.952 mL.

The Plaintiffs

Tulsa Cancer Institute

20. At times relevant to this action, TCI was a physician-owned specialty medical practice that provided multidisciplinary care for patients

with cancer and other blood disorders and was recognized for its clinical trials to evaluate new treatments conducted in collaboration with cancer patients. The clinical studies were regulated and approved by the United States Food and Drug Administration ("FDA") and designed to find new drugs, new combinations of drugs, and/or innovative ways to treat cancer and improve the quality of patient care and outcomes.

Cancer Care Associates

21. CCA previously operated a blood and cancer disease organization, treating patients under the trade name Cancer Care Associates, PC. In 2013, it closed its medical clinic and began operating as an administrative services organization, providing services to various medical practices on a contract basis.

The University of Oklahoma Stephenson Cancer Center

22. The Stephenson Cancer Center provides a comprehensive range of diagnostic and treatment options, specializing in almost every area of cancer treatment or research, including: medical oncology, radiation oncology, pediatric oncology, gynecological oncology, blood disorders and bone marrow transplant. Cancers suffered by women are a special area of emphasis for the OU Stephenson Cancer Center. Doctors, board-certified in gynecological oncology, are actively involved in medical

research to find new and more effective treatments in the fight against female cancers.

Texas Oncology

23. Founded in 1986, Texas Oncology is a pioneer in community-based cancer care. It is an independent oncology practice with more than 375 physicians and 150 locations across Texas and southeastern Oklahoma, including 48 comprehensive cancer centers. Texas Oncology medical teams specialize in medical oncology, hematology, gynecologic oncology, pediatric hematology and oncology, and radiation oncology.

Factual Allegations (All Individual and Class Action Claims)

Herceptin's Purpose

24. The cancer drug which forms the basis for the claims in this lawsuit is Herceptin (trastuzumab). Herceptin is used to treat patients with metastatic breast cancer and tumors that overexpress the HER2 gene. Herceptin is widely-used and, with many patients, is an effective drug to reduce and deter the growth of malignant breast cells. Herceptin is approved by the FDA as an adjuvant therapy for breast cancer and for metastatic, gastric cancer which has tested positive for HER2 receptor sites.

25. The HER2 gene makes HER2 proteins, which are receptors on breast cells. Normally, HER2 receptors help control how a healthy breast

cell grows, divides, and repairs itself. In about 25% of breast cancers, the HER2 gene fails to work correctly and makes too many copies of itself (known as HER2 gene amplification). The extra HER2 genes allow breast cells to make too many HER2 receptors; referred to as HER2 protein overexpression. This makes breast cells grow and divide in an uncontrolled way. Breast cancers with HER2 gene amplification or HER2 protein overexpression are called HER2-positive. HER2-positive breast cancers tend to grow faster and are more likely to spread and return after treatment compared to HER2-negative breast cancers.

26. Genentech manufactures and distributes Herceptin. Since 1998, Plaintiffs have purchased Herceptin, used in the treatment of their patients.

27. Genentech markets itself as a research-driven corporation. Genentech employs more than 1,100 researchers, who cover a wide range of scientific activity-from molecular biology to protein chemistry, bioinformatics and physiology. Genentech scientists claim to focus their efforts on five disease categories including oncology, immunology, tissue growth and repair, neuroscience and infectious disease.

28. Genentech markets and distributes Herceptin through a closed distributor network. Genentech sends its own representatives to Plaintiffs'

offices. Genentech also administers rebate and discount programs in which Plaintiffs are participants.

29. Herceptin is the only cancer medication currently on the market that effectively treats metastatic breast cancer and tumors that overexpress the HER2 gene.

Herceptin's FDA Approved Preparation Instructions

30. In 1998, Genentech submitted and the FDA approved a Label for Herceptin.

31. The 1998 FDA-approved Label provided a Preparation for Administration section that instructed: "Use appropriate aseptic technique. Each vial of HERCEPTIN should be reconstituted with 20mL of BWFI, USP, 1.1% benzyl alcohol preserved, as supplied, to yield a multi-dose solution containing 21 mg/mL Trastuzumab."

32. The FDA-approved Prescribing Information (or "Label") has been modified several times since 1998.

33. Each FDA-approved Prescribing Information for Herceptin included that same basic instruction, including the most recent April 2015 revised Prescribing Information: "Reconstitute each 440 mg vial of Herceptin with 20 mL of Bacteriostatic Water for Injection (BWFI), USP, containing 1.1% benzyl alcohol as a preservative to yield a multi-dose solution containing 21 mg/mL trastuzumab."

34. Herceptin is manufactured as a lyophilized (dehydrated and "freeze-dried" powder) medicine which is delivered in vials, labeled by Genentech as containing 440 milligrams (mg) of Herceptin. The Herceptin product is mixed with a liquid (diluent), also provided to end users by Genentech. The mixing process is accomplished by injecting the diluent into the vial containing the lyophilized Herceptin.

35. This mixing process reconstitutes each vial of Herceptin into a multi-dose fluid solution.

36. Genentech represents and warrants that the resulting multi-dose fluid solution is concentrated at a density of 21 mg/mL.

37. 440 mg reconstituted into a fluid solution with a density of 21 mg/mL would result in 20.952 mL of fluid solution: 440 mg divided by 21 mg/mL.

The Herceptin Shortage

38. Plaintiffs have discovered that they cannot obtain 20.952 mL of fluid solution by following the Preparation of Administration instructions provided by Genentech and approved by the FDA.

39. Plaintiffs do not obtain more than 20.2 mL of fluid solution by following the Preparation of Administration instructions provided by Genentech and approved by the FDA.

40. These multi-use vials were and are used by Plaintiffs to administer Herceptin to their patients based on each patient's prescribed treatment dosage.

41. Plaintiffs have evaluated laboratory testing performed on the reconstituted Herceptin. The laboratory testing determined, after the diluent provided by Genentech is mixed with the product, each vial yields no more than 20.2 mL of fluid solution rather than the 20.952 mL that would follow mathematically from Genentech's representations and warranties.

42. The reconstituted Herceptin does not contain 440 mg of Herceptin and/or is not a fluid solution with density 21 mg/mL.

43. Plaintiffs rely upon Genentech's representation that the concentration of the fluid solution is 21 mg/mL when administering the proper dosage to each patient. In administering the Herceptin from the multi-use vials, Plaintiffs withdraw the amount of reconstituted Herceptin medicine necessary for each patient until each vial was emptied.

44. Relying on Genentech's representation that the fluid solution density is 21 mg/mL, Plaintiffs provide sufficient volume of the fluid solution to administer the proper dosage of Herceptin. For example, a person weighing 50 kg should receive 200 mg of Herceptin for her initial

dose. To administer 200 mg of Herceptin, Plaintiffs would provide 9.52 mL of fluid solution: 200mg divided by 21 mg/mL.

45. If Genentech's representation that the fluid solution density is 21 mg/mL is accurate, then Genentech is providing, at most, 424 mg of Herceptin: 20.2 mL multiplied by 21 mg/mL. If Genentech is providing 424 mg or less of Herceptin, Genentech is providing less medicine than represented and warranted, and causing Plaintiffs to purchase additional Herceptin.

46. If Genentech's representation that the Herceptin vial contains 440 mg of Herceptin is accurate, then the fluid solution density is, at least, 21.8 mg/mL: 440 mg divided by 20.2 mL. If Genentech is providing instructions and product that create a fluid solution density of at least 21.8 mg/mL, Genentech is causing Plaintiffs to administer an overdose by representing the fluid solution density is 21 mg/mL, and causing Plaintiffs to purchase additional Herceptin.

47. Either way, Plaintiffs are forced to purchase additional Herceptin because following Genentech's Preparation of Administration instructions yields less volume of fluid solution than mathematically follows from Genentech's representation and warranties.

First Claim - Breach of Express Warranty

48. Plaintiffs adopt the allegations contained in paragraphs 1 through 47 and further allege and state:

49. Beginning in 1998, Plaintiffs relied on all representations and warranties made by Genentech concerning the quantity of Herceptin purchased from Genentech.

50. Beginning in 1998, Plaintiffs relied on all representations and warranties made by Genentech concerning the density of the fluid solution of reconstituted Herceptin purchased from Genentech.

51. In Plaintiffs' experience, reconstituting each vial of Herceptin yields no more than 20.2 mL rather than the 20.952 mL that follows mathematically from Genentech's representations and warranties.

52. Genentech's representations and warranties were material to Plaintiffs and were material to their purchase and use of Herceptin.

53. Genentech's false representations and warranties relied upon by Plaintiffs include:

a. Each vial purchased by Plaintiffs contains 440 mg of Herceptin.

b. Each reconstituted vial of Herceptin yields fluid solution with a density of 21 mg/mL.

c. Each reconstituted vial of Herceptin contains 20.952 mL of fluid solution. This representation follows mathematically from the two statements above: 20.952 mL equals 440 mg divided by 21 mg/mL.

54. As a result of Genentech's breach of express warranty, Plaintiffs were damaged due to the additional vials of Herceptin they were forced to purchase.

Second Claim - Breach of Implied Warranty

55. Plaintiffs adopt the allegations contained in paragraphs 1 through 54 and further allege and state:

56. Under the implied warranty of merchantability, Genentech was required to provide goods that were consistent in kind, quality, and quantity with the representations concerning the Herceptin product.

57. Genentech breached its warranty of merchantability by providing Plaintiffs with Herceptin that did not meet the quantity represented and warranted by Genentech.

58. As a result of Genentech's breach of implied warranty, Plaintiffs were damaged due to the additional vials of Herceptin they were forced to purchase.

Third Claim - Unjust Enrichment

59. Pleading in the alternative, in the event the Court determines the Plaintiffs do not have an adequate remedy at law based on Genentech's breach of warranties, Plaintiffs adopt the allegations contained in paragraphs 1 through 58 and further allege and state:

60. Genentech has received an unfair benefit through its practice of providing vials and product that yield only 20.2 mL of usable Herceptin fluid solution, but receiving payment for 20.952 mL of product for each vial sold.

61. Under the circumstances, as alleged herein, the retention of that benefit would unjustly enrich Genentech.

62. Plaintiffs have suffered economic damages while Genentech has enjoyed unjust enrichment.

CLASS ACTION ALLEGATIONS

63. This action is brought by the Plaintiffs individually and as class representatives against Defendant Genentech to recover damages for themselves and for all others similarly situated. The damages sought in this class action are limited to those that result from a breach of warranties and, possibly, unjust enrichment. This class action is not asserting any claims based on any tort theories of recovery. Plaintiffs seek economic

damages on behalf of themselves and each putative class member based on the amount each purchaser overpaid for Herceptin.

The Class Definition

64. Plaintiffs propose to represent a class defined as all entities that purchased and administered Herceptin in the United States marked with warranties provided by Genentech (the "Class Members"). The Class Members do not include: (1) Genentech affiliates, employees, directors, and officers, and members of their immediate families; or (2) judges before whom this case is pending and persons within the fourth degree of consanguinity or affinity to them.

65. Plaintiffs reserve the right to amend or modify the Class definition with greater specificity or to divide the Class into subclasses or limitation to particular issues.

The Class Is Too Numerous For All Class Members To Prosecute Individual Claims

66. On information and belief, the Class Members include hundreds, if not thousands, of entities. Joinder of each Class Member as a party to this action is not practical.

The Common Questions Of Law And Facts Predominate Over Individual Claims

67. There are questions of law and fact common to the claims asserted by the Plaintiffs and each Class Member against the Defendant. The common questions of law and fact include, but are not limited to:

(1) whether Genentech warrants that Herceptin vials contain 440 mg of Herceptin as stated in the FDA-approved label;

(2) whether Genentech breached its warranty that Herceptin vials contain 440 mg of Herceptin by failing to provide that quantity;

(3) whether Genentech warrants that Herceptin reconstituted according to the instructions on its FDA-approved label has a concentration of 21 mg/mL;

(4) whether Genentech breached its warranty that Herceptin reconstituted according to the instructions on its FDA-approved label has a concentration of 21 mg/mL;

(5) whether Genentech warrants a specific volume of reconstituted Herceptin;

(6) whether Genentech breached its warranty by failing to provide the specific volume of reconstituted Herceptin warranted;

68. The common questions of law and fact predominate over any questions affecting each Class Member individually, thus a class action is superior to other available methods for the fair and efficient adjudication

of this controversy. There should be no unusual difficulties in the management of this case as a class action.

Plaintiffs' Claims Are Typical Of The Class Members' Claims

69. Plaintiffs' claims are typical of the claims of each Class Member, and the Plaintiffs will fairly and adequately represent the interests of the class and each Class Member. The claims of the Plaintiffs and each Class Member are based on the warranties provided by Genentech on the packaging and in the FDA-approved literature distributed with each package of Herceptin. All Plaintiffs and all Class Members purchased Herceptin in the same packages and received the same warranties. Plaintiffs have suffered the same type of damages as each Class Member and the damages of Plaintiffs and the Class Members are measured in the same way.

Plaintiffs and Their Counsel Will Adequately Represent the Class

70. Counsel for Plaintiffs and the Class Members are experienced and knowledgeable concerning complex business and class-action litigation. All counsel for Plaintiffs and the Class Members are licensed in Oklahoma and are admitted to practice in the Northern District of Oklahoma. For approximately 15 months (since April 3, 2015), Plaintiffs' counsel have represented the Plaintiffs and numerous other parties with claims against Genentech for breaches of warranties related to Herceptin.

Plaintiffs' counsel will fairly and adequately represent the interests of the putative class.

A Class Action Is The Superior Way To Manage The Claims And Defenses That May Be Asserted

71. This action is properly maintainable as a class action because separate adjudications could result in inconsistent or varying adjudications which would establish incompatible standards of conduct for the Defendant. Adjudication of Plaintiffs' claims would, as a practical matter, be dispositive of the claims of the other Class Members. Concentrating the claims of each Class Member in a single lawsuit will result in judicial efficiency and will not prejudice the rights of Genentech or any Class Member. Although individual claims could be prosecuted, due to the common conduct of Genentech and the common issues of law and fact applicable to Plaintiffs and Genentech, a class action is the superior way for Genentech to respond to the claims and for the Plaintiffs and the Class Members to prosecute their claims.

Notice to the Class

72. Plaintiffs contemplate that the eventual issuance of notice to the proposed Class members would set forth the subject and nature of this action. Plaintiffs believe Defendant's records, or records of Herceptin distributors, as to the names and addresses of purchasers of the product at issue are sufficient for direct mail notice to reach the vast majority of

Class Members. To the extent that any further notices may be required, published notice in appropriate professional publications and journals can also be provided.

Request for Relief

WHEREFORE, Plaintiffs, for themselves and on behalf of a Class similarly situated, respectfully request the following relief:

1. Entry of an order certifying the proposed Class under Fed. R. Civ. P. 23(a) and (b)(2) and/or (b)(3) and appointing Plaintiffs and their counsel to represent the Class under Fed. R. Civ. P. 23(g).
2. Entry of a judgment against Genentech for all damages suffered by Plaintiffs and the Class in an amount to be determined at trial;
3. Prejudgment and post-judgment interest on all damages;
4. A declaration that Genentech is financially responsible for notifying Class Members of the pendency of this suit;
5. An award providing for payment of reasonable costs of suit;
6. An award for attorneys' fees; and
7. All other and further relief this Court deems just and proper.

Respectfully Submitted,

/s/ David E. Keglovits

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ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of June, 2016, I electronically transmitted the foregoing document to the Clerk of the Court using the ECF System for filing.

/s/ David E. Keglovits
David E. Keglovits

Hope this helps.

Jeff

Subject: Content of Herceptin vials
Date: Wed, 25 Sep 2002 11:52:19 -0700
From: Tom White <twhite@gene.COM>
Organization: Genentech, Inc.
To: Olivia Ware <ware.olivia@gene.COM>
CC: William Henry Smith <smith.william@gene.COM>

Genentech's Herceptin Production Engineer

The following data should correct the misconception of the pharmacy department at US Oncology that we are not filling 440 mg of Herceptin in our vials. Their assumption is based on the package insert statement that the concentration of Herceptin in the vial is 21 mg/ml and it is reconstituted with 20 ml of diluent.
(21 x 20+_ 0.5 ml = 409.5 to 430.5mg)

In actuality we fill 18 ml of bulk solution at a concentration of 25 mgs/ml into the vial and lyophilize. We therefore target 450 mg in a vial (and nominally state 440 mg). (18 x 25 = 450 mg)

Our technical report supporting the IND Studies of Lyophilized Multi-dose Her2 Formulation written in 1996 states that the reconstituted volume after adding 20 ml of diluent is actually about 20.6 ml due to the volume expansion of the solids present in the vial. Hence the theoretical concentration of the reconstituted product is actually 21.8 mg/ml. (450 mg/20.6 ml = 21.8mg) After internal discussion in 1996, it was decided to round down the concentration in the insert to the nearest whole number rather than round up to a concentration we in fact do not achieve (ie. 22mg/ml). I believe this is the source of the confusion.

Whereas we actually have between 440 and 450 mg in our vials they calculate that it is less.
(21.8 mg/ml x 20.6 ml) vs (21 mg/ml x 20 ml)

Let me know if this fully addresses their concern or if further explanation is necessary.